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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,907	10/13/2006	Pavak R. Mehta	GEN 3.3-014	6487

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,907	MEHTA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/06; 4/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Response to Restriction/Election requirement, the Amendment and Applicant's Arguments/Remarks, all filed 08/09/10 and the Information Disclosure Statements (IDS) filed 10/13/06 and 04/24/08.

Applicant's election with traverse of "composition claims" (claims –13, 21 and 22) in the reply filed on 09 August 2010 is acknowledged. The traversal is on the ground(s) that "All of the claims now are directed to pharmaceutical dosage forms that comprise a tablet, or the production thereof; the only independent claim is claim 1. Each of presently amended claims 2-23 incorporates, directly or indirectly, all of the limitations of claim 1. The presence of a single inventive concept should be presumed, in the absence of evidence that a unifying concept is not patentable." This was found persuasive by virtue of the amendment to the claims. Accordingly, the restriction requirement filed 07/09/10 for Groups I-IV and election of species for Group IV is hereby withdrawn.

Claims 1-23 are pending in this action. Claims 1-9, 13-17, 20 and 21 have been amended. Claims 1-23 have been examined in this action. Claims 1-23 are rejected.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250).

Batycky *et al.* ('250) discloses particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

The particles of the invention have a mean particle size of about 5 to about 50 microns (p. 3, [0029]). The morphology of the instant particles contributes to enhanced dispersibility and stability by decreasing the area of contact between the particles (p. 3, [0030]). The particles can deliver at least about 5 mg of the drug and the powder can be compressed about 10 to about 29 times. Even when compressed, the particles still retain the improvement in dissolution rate (p. 3, [0030]). Suitable excipients for use in the formulation are disclosed at p. 4, [0035-0037].

In one embodiment, the invention provides for an important feature for conferring pharamacokinetic/pharmacodynamic solubility to a poorly soluble drug, whereby the feature is dissolving a crystalline drug to form a solution and spray drying the solution thereby making the drug amorphous and small without damaging bioactivity and concurrently making the particle comprising the amorphous drug. The combination of now small and amorphous drug embedded in the amorphous thin walled particle confers surprising solubility when compared to the bulk drug (p. 7-8, [0087]).

The compounds of the invention can be provided in various administration forms, including, for example, uncoated or (film-)coated tablets, capsules, powders, granules and the like as well as particle-filled capsules (p. 8, [0096-0097]). In one embodiment, the particles have a dissolution rate enhancement of at least 2-fold compared to the bulk drug (p. 9, [0098]); (p. 10, [0122]).

Suitable active compounds are disclosed at p. 9, [0101] and include, for instance, lansoprazole, olanzapine and the like.

Thus, Batycky discloses pharmaceutical dosage forms in the form of compressed tablets or powder/particle-filled capsules which contain poorly soluble active agents that would be susceptible to polymorphic conversion, and discloses that the process of formulating the dosage forms enables particles comprising the amorphous drug whereby bioactivity is not damaged and polymorphic stability is maintained. The instant specification, at page 2, lines 23-28, further evidences that "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms".

The instant claims are anticipated by Batycky.

* * * * *

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Babcock *et al.* (U.S. Pat. Appln. Pub. No. 2003/0104063).

Babcock *et al.* ('063) discloses pharmaceutical compositions comprising a dispersion of amorphous, low-solubility drugs combined with concentration-enhancing polymers for enhancing and improving the stability of a drug (see Abstract); (p. 1, [0002]-[0004]). Babcock discloses that a least a major portion of said drug in the dispersion is amorphous and is preferably almost completely amorphous, whereby the amount of drug in the amorphous form is at least 90% (p. 1, [0012-0014]); (p. 2 [0030]); (p. 59, [1211]. This reads on Applicant's limitation of claim 3. Suitable active agents disclosed include cholesterol-lowering agents and other low-solubility drugs (p. 4, [0052]); (p. 6-7, [0077-0080]). The pharmaceutical compositions may be prepared according to methods disclosed at p. 69, [1294-1298]. The compositions can be provided in various administration forms, including, for example, tablets, capsules, suspensions, powders, multiparticulates, pills and the like. Excipients can be mixed with the concentration-enhancing polymer to form different beads, or layers or coatings or cores or separate dosage forms (p. 72, [01316]-[1319]); (p. 73, [1327]).

The instant claims are anticipated by Babcock.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5 and 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250).

Batycky *et al.* ('250), as discussed above, teaches particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

The particles of the invention have a mean particle size of about 5 to about 50 microns (p. 3, [0029]). The morphology of the instant particles contributes to enhanced dispersibility and stability by decreasing the area of contact between the particles (p. 3, [0030]). The particles can deliver at least about 5 mg of the drug and the powder can be compressed about 10 to about 29

times. Even when compressed, the particles still retain the improvement in dissolution rate (p. 3, [0030]). Suitable excipients for use in the formulation are disclosed at p. 4, [0035-0037].

In one embodiment, the invention provides for an important feature for conferring pharamacokinetic/pharmacodynamic solubility to a poorly soluble drug, whereby the feature is dissolving a crystalline drug to form a solution and spray drying the solution thereby making the drug amorphous and small without damaging bioactivity and concurrently making the particle comprising the amorphous drug. The combination of now small and amorphous drug embedded in the amorphous thin walled particle confers surprising solubility when compared to the bulk drug (p. 7-8, [0087]).

The compounds of the invention can be provided in various administration forms, including, for example, uncoated or (film-)coated tablets, capsules, powders, granules and the like as well as particle-filled capsules (p. 8, [0096-0097]). In one embodiment, the particles have a dissolution rate enhancement of at least 2-fold compared to the bulk drug (p. 9, [0098]); (p. 10, [0122]).

Suitable active compounds are disclosed at p. 9, [0101] and include, for instance, lansoprazole, olanzapine and the like.

Thus, Batycky discloses pharmaceutical dosage forms in the form of compressed tablets or powder/particle-filled capsules which contain poorly soluble active agents that would be susceptible to polymorphic conversion, and discloses that the process of formulating the dosage forms enables particles comprising the amorphous drug whereby bioactivity is not damaged and polymorphic stability is maintained.

While Batycky does not explicitly teach the compression parameters of instant claims 4, 5, 9, 12, 14 and 18, the reference is nonetheless suggestive of formulations comprising amorphous drugs, whereby the particles, even when compressed, still retain the improvement in dissolution rate (p. 3, [0030]) and maintain polymorphic stability without damaging bioactivity. The formulation clearly provides for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]). Moreover, the determination of suitable or effective compression forces can be obtained by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Furthermore, the instant specification, at page 2, lines 23-28, further evidences that "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms".

With respect to the dimensions of the tablet ("about 3 mm" or "about 1 mm to about 3 mm") as in instant claims 13, 15 and 19, Batycky meets these limitations, as their particles have a mean particle size of about 5 to about 50 microns (p. 3, [0029]).

Regarding instant claim 17, Batycky teaches the use of both coated and uncoated tablets, as well as capsules, powders, granules and particle-filled capsules, for example (p. 8, [0096-0097]).

With respect to claim 9, which recites product-by-process limitations, the Examiner notes "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In any event, Batycky meets the product-by-process limitations, based on their teachings at (p. 1, [0010]; p. 2, [0014]), whereby the active agent is mixed with one or more excipients, as further discussed below.

With respect to claim 14, which recites a method of preparing the pharmaceutical dosage form, Batycky meets these limitations. Batycky discloses a method for preparation whereby the particles may comprise one or more drugs, wherein the drug forms a solid solution with one or more excipients, such as for example, where a drug is molecularly dispersed with one or more excipients and/or wherein a drug is present is regions of drug-rich material (p. 1, [0010]; p. 2, [0014]).

Regarding instant claims 2, 10 and 16, Batycky teaches active agents that are amorphous. See p. 9, [0101], whereby suitable active agents disclosed include lansoprazole, olanzapine and the like.

Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Batycky discussed above.

* * * * *

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250), as applied to claims 1, 3-5 and 9-20 above and further in view of Khanna *et al.* (U.S. Pat. Appln. Pub. No. 2008/0119654).

Batycky *et al.* ('250), as discussed above, teaches particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

Batycky teaches active agents that are amorphous. See p. 9, [0101], whereby suitable active agents disclosed include lansoprazole, olanzapine and the like.

Batycky does not teach esomeprazole magnesium (as in instant claims 21-23).

Khanna *et al.* ('654) teaches amorphous forms of esomeprazole salts, i.e., esomeprazole magnesium and methods for the preparation thereof (see Abstract); p.1, [0001-0010]. The pharmaceutical composition includes carriers, excipients and diluents (p. 1, [0012]. The pharmaceutical composition may be used in the treatment of gastric-related diseases (p. 2, [0023]. The compositions can be provided in various administration forms, including, for example, tablets, capsules, pills and the like (p. 2, [0031]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as esomeprazole magnesium, as taught by Khanna within the formulations of Batycky. One would do so with a reasonable expectation of success because Khanna discloses amorphous forms of esomeprazole salts, i.e., esomeprazole magnesium for the effective treatment of gastric-related diseases and evidences that it is well-

known to provide for cholesterol-reducing agents in amorphous forms. The expected result would be an improved pharmaceutical composition for the effective treatment of gastric-related disorders and conditions.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

October 25, 2010